UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

Office of Pesticide Programs

Antimicrobials Division (AD)

May 29, 2014

DP BARCODE: 419921

MRID: 49351700 and 49351701

SUBJECT: SilvaDur™

REG. NO.: 707-313

DOCUMENT TYPE: Product Chemistry Review

Manufacturing-use [ ] OR End-use Product [X]

INGREDIENTS:

PC Code(s)	CAS Number	Active Ingredient:
072501	74401-22-4	Silver

TEST LAB: Dow Microbial Control

SUBMITTER: The Dow Chemical Company

GUIDELINE: Product Chemistry

ORGANIZATION: AD\PSB\CTT

REVIEWER: Lynette T. Umez-Eronini

APPROVED BY: Karen P. Hicks

APPROVED DATE: May 29, 2014

COMMENT: This product is for non-food use.

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May 29, 2014

MEMORANDUM

SUBJECT: Product Chemistry Review for EPA Reg. 707-313
Product Name: SilvaDur™
DP Barcode: 419921

FROM: Lynette T. Umez-Eronini, Chemist
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

THRU: Karen Hicks, Team Leader
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

TO: Marshall Swindell PM#33/Zebora Johnson
Regulatory Management Branch I
Antimicrobials Division (7510P)

Applicant: Rohm & Haas Co.

CODE: 360 Action Initiated by the Agency;

DATE DUE: June 19, 2014

PRODUCT FORMULATION FROM LABEL:

Active Ingredient(s):	% by wt.
Silver	2.95
Inert Ingredient(s):	97.05
Total:	100.0

BACKGROUND:

The Dow Chemical Company has submitted Storage Stability and Corrosion Characteristics studies in support of the registration of an integrated end-use product called SilvaDur™. Prior studies conducted by Rohm & Haas were not found after acquisition of the company by Dow. The product is an antimicrobial preservative for odor control in the manufacturing of coatings, films and fibers. The product is for non-food contact use.

The product chemist reviewed the following documents:

1. Cover letter from Registrant to EPA, 3/27/2014.
2.

49351700	Cover letter same as Transmittal Document, 3/17/2014: Rohm & Haas Company (2014) Submission of Product Chemistry Data in Support of the Registration of SilvaDur. Transmittal of 1 Study.
49351701	Nagahashi, S. (2008) Storage Stability and Container Compatibility of QR-1727. Project Number: 24P/2006/101, GLP/2008/121, GLP/2008/120. Unpublished study prepared by Rohm and Haas Company. 44p.

FINDINGS:

1. Basic CSF, 4/15/2014 and product label, 4/28/2010 are used as references.
2. Storage stability and corrosion characteristics studies were done on test product (sample) stored in high molecular weight high density polyethylene HMWHDPE bottles and double phenolic lined carbon steel (CS) containers for 2 years at 1, 2. 3, 6, 9, 12, 18, and 24 months, at a constant room temperature (CTR) of 75 ± 2 °F and at a 50 ± 2% relative humidity (RH).
3. The active ingredient was determined by titration.
4. Studies using the CS containers were discontinued after 3 months due to the test product being incompatible with the CS containers and causing extreme color changes and deterioration of the said containers.
5. The study was conducted in compliance with U.S. EPA Good Laboratory Practice Standards 40 CFR Part 160.
6. The results of the storage stability and corrosion characteristics studies are shown in the table below:

Summary Table of Storage Stability and Corrosion Characteristics Studies Results

Analysis Time	Average Ag^+, %	Physical Observation of Test Sample	Physical Observation of Test Container	Average Ag Remaining, %
Initial (0 Month)	3.0558	Clear, yellow	---	
1 Month	3.0598 ± 0.0041	Slightly hazy, golden yellow	HMWHDPE: nothing visual; appears normal	100.1309
2 Months	3.0751 ± 0.0122	Slightly hazy, gold	HMWHDPE: slightly discolored on bottom	100.6316
3 Months	3.0817 ± 0.0142	" "	" "	100.8476
6 Months	3.0663 ± 0.0124	" "	" "	100.3426
9 Months	3.0840 ± 0.0298	" "	HMWHDPE: slightly discolored on bottom; noticed flaking of discolored bottom film	101.9228
12 Months	3.0882 ± 0.0181%	" "	" "	101.0603
18 Months	3.0191 +0.1287%	" "	" "	98.7990
24 Months	3.0866 ± 0.0196	" "	" "	101.0079

7. Active — Nominal — Certified Limit
   Silver (formed from silver nitrate) — 2.95 — 2.35 – 3.55
8. The certified limits for the active ingredient meet the EPA Standard Certified Limits.
9. Weight loss from samples during storage due to evaporation of solvent was done by measuring the difference in mass between the container plus sample and the empty container for the sampling times. This showed no significant difference in % content of the active ingredient in the test samples.
10. Titration results show no significant change in the concentration of active ingredient in the product over the 24 months.
11. The physical appearance of the test sample had basically not changed.
12. The physical appearance of the HMWHDPE container after 2 months showed that it was slightly discolored on the bottom throughout the remaining months of the study and at 9 months and thereafter showed flaky discolored film on

the bottom of the bottle (container). However, the physical appearance of the test sample had basically not changed nor had the chemical characteristics of the active ingredient changed.

13. No significant signs of deterioration/leaks were observed in the storage container material during two year storage stability and corrosion characteristics studies.

CONCLUSION:

The results of the two year storage stability and corrosion characteristic studies show that the concentration of active ingredient is maintained within the range of the certified limits for the active in the product. Neither the product nor its packaging showed any significant signs of deterioration. The study provided is found to be acceptable.